510(K) Summary

JUL 20 2001

## ADMINISTRATIVE INFORMATION


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| Manufacturer Name: | MacroPore, Inc.<br>6740 Top Gun Street<br>San Diego, CA 92121 |
| Official Contact: | Kenneth K. Kleinhenz<br>Director of Regulatory Affairs<br>Telephone (858) 458-0900<br>Fax (858) 458-0994 |


## DEVICE NAME

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|---|---|
| Classification Name: | Appliance, Fixation, Spinal Intervertebral Body |
| Trade/Proprietary Name: | MacroPore *OS* Spinal System |

## ESTABLISHMENT REGISTRATION NUMBER

2031733

## DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 888.3060 Appliance, Fixation, Spinal Intervertebral Body devices intended for use in spinal plating procedures are classified as Class II. They have been assigned Product Code KWQ.

## INTENDED USE

MacroPore *OS* Spinal System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing indications.

**Design Characteristics**
MacroPore *OS* Spinal System is a resorbable graft containment system composed of various sized porous sheets, non-porous sheets, and associated fixation screws fabricated from polylactic acid (PLA). The MacroPore *OS* Spinal System is composed of MacroPore *OS* Protective Sheets and MacroPore *OS* Spinal Screws. MacroPore *OS* Protective Sheets can be cut with scissors to the desired shape and size. The MacroPore Power Pen can also be used to cut or shape the MacroPore *OS* Protective Sheets to the desired shape or size. The MacroPore *OS* Protective Sheet is fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation.

The MacroPore *OS* Spinal System includes a selection of resorbable screws and associated manual instruments. Screws range in size from 2.0mm to 4.8mm in outer diameter. The MacroPore *OS* Protective Sheets come in various sizes ranging from 0.75mm to 3.0mm in thickness according to the region to be treated. The MacroPore *OS* Protective Sheets range in size from as small as 50mm x 50mm to as large as 120mm x 120mm. The MacroPore *OS* Protective Sheet is provided with and without macroporous holes. The macroporous holes range in size from 500 microns to 3,000 microns in diameter. Various manual instruments (screw drivers, taps, drill bit, etc.) are used in conjunction with the MacroPore *OS* Spinal System to assist in the installation process.

**Material Composition**
The MacroPore *OS* Protective Sheet is fabricated from polylactic acid (PLA).

**In Vitro Testing**
Because the MacroPore *OS* Protective Sheet is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. Therefore, the relatively brief exposure anticipated during the surgical preparation of MacroPore *OS* Protective Sheet is not expected to have a significant effect on its mechanical properties.

Aging studies were performed on MacroPore *OS* Spinal System components. Testing demonstrated that the MacroPore *OS* Protective Sheet is as rigid and as strong as the predicate after 6 month of exposure. Mechanical testing was performed on the MacroPore *OS* Protective Sheets and MacroPore *OS* Spinal Screws. Testing determined the MacroPore *OS* Spinal System to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

Crystallinity was tested for by DSC (differential scanning calorimetery). This test measures the amount of heat energy that is absorbed by a material. A crystalline material will require more energy once it reaches it's melting point. This release of heat energy can be seen on a graph as a sharp spike and is referred to as a "melting endotherm". The tests ran on the sterile and non-sterile samples revealed no endothermic spikes, indicating that the implants are amorphous and non-crystalline.

**In Vivo Testing**
Studies were conducted to demonstrate strength over time, safety, and biocompatibility of the MacroPore *OS* materials in vivo. These studies demonstrated that the MacroPore *OS* materials is appropriate for the intended use.

**EQUIVALENCE TO MARKETED PRODUCT**
The MacroPore *OS* Spinal System shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: Sofamor Danek Bone Graft Washer, and the MacroPore *OS* Protective Sheet.

**Indications For Use**
The MacroPore *OS* Spinal System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing indications. The MacroPore *OS* Spinal System shares substantially equivalent indications for use principles with the predicate devices.

**Design and Materials**
The physical designs of the MacroPore *OS* Spinal System and the Sofamor Danek Bone Graft Washer are substantially equivalent as they both utilize a solid plate or sheet that is secured with screws. The MacroPore *OS* Spinal System and the MacroPore *OS* Protective Sheeting predicate are substantially equivalent. The design features of the MacroPore *OS* Spinal System are substantially equivalent to the predicate device as both devices utilize flat sheet designs of similar shapes and sizes containing multiple holes that accept a screw. The mechanical characteristics of the MacroPore *OS* Spinal System are substantially equivalent to the predicate device as the MacroPore *OS* Spinal System has greater mechanical strength than the MacroPore *OS* predicate. The materials used in both the MacroPore *OS* Spinal System and the predicate device are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2001

Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
MacroPore, Inc
6740 Top Gun Street
San Diego, California 92121

Re: K010911
Trade/Device Name: MacroPore OS Spinal System
Regulation Number: 888.3030, 888.3060, 888.3040
Regulatory Class: II
Product Code: KWQ, HRS
Dated: June 21, 2001
Received: June 25, 2001

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010911

Device Name: **MacroPore*OS*** Spinal System

**Indications for Use:**
MacroPore *OS* Spinal System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing indications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010911